| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D0526797 | 04/25/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Planned Parenthood Arizona - Central Phoenix | 4751 N 15th St, Phoenix, AZ | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Proficiency Testing (PT) records for review from 2022 and 2023 and interview with the technical consultant (TC-2), the laboratory failed to maintain a copy of all PT records for a minimum of 2 years from the date of the proficiency testing event. Findings include: 1. The laboratory performs D(RHO) testing on patient specimens using the EldonCard RhD test kit under the specialty of Immunohematology, with a reported annual test volume of 2,720. 2. During the survey conducted on 4/25/2024, the laboratory failed to produce evidence of the following PT documentation from the second and third testing events of 2023: - Attestation statements signed by the Laboratory Director and testing personnel - Copy of the PT program report form used by the laboratory to record PT results 3. The TC-2 interviewed on 4/25/2024 at 11:06 AM confirmed that the PT records indicated above could not be produced during the survey. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g) |

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| | Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Quality Control (QC) documentation and interview with the technical consultant (TC-2), the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Immunohematology. Findings include: 1. The laboratory performs D (RHO) testing on patient specimens using the EldonCard RhD test kit under the specialty of Immunohematology, with a reported annual test volume of 2,720. 2. The laboratory's 'Laboratory Visit Log' states: "Eldon Card: Perform controls each day test will be used to determine Rh factor on patients." 3. The laboratory failed to perform and document external QC using positive and negative control materials on 8/22 /2023. Three patient tests were performed on 8/22/2023. 4. The TC-2 interviewed on 4 /25/2024 at 11:05 AM confirmed the laboratory failed to perform and document external quality control procedures for the day listed above. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality assessment (QA) records and interview with the technical consultant (TC-2), the laboratory failed to identify errors found within the analytic systems. Findings include: 1. The laboratory performs patient testing under the specialty of Immunohematology, with an approximate annual test volume of 2,720. 2. Based on interview with the TC-2 on 4/25/2024 at 11:25 AM, it is the practice of the laboratory to perform and document a monthly QA review on a form titled, "Health Center Monthly Report Form". 3. No corrective action documentation was provided for review to indicate the laboratory identified errors associated with quality control performance and documentation. See D5445 for findings. 4. The TC-2 interviewed on 4/25/2024 at 11:25 AM confirmed that the laboratory's quality assessment activities were not effective in identifying and correcting problems found within the analytic systems, specifically with quality control performance and documentation. |